IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SALIX PHARMACEUTICALS, INC. and
DR. FALK PHARMA GmbH,

Plaintiffs/Counter-Defendants,

v. **CIVIL ACTION NO. 1:15CV109**
(Judge Keeley)

MYLAN PHARMACEUTICALS, INC. and
MYLAN, INC.,

Defendants/Counter-Claimants.

MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS

This patent infringement case involves four United States patents issued to the plaintiff, Dr. Falk Pharma GmbH, and licensed by the plaintiff, Salix Pharmaceuticals, Inc. (collectively, "Salix"). These include: Patent No. 6,551,620 ("the '620 Patent"); Patent No. 8,337,886 ("the '886 Patent"); Patent No. 8,496,965 ("the '965 Patent"); and 8,865,688 ("the '688 Patent"). The '620, '886, and '965 Patents, collectively referred to as the Otterbeck patents,[1] contain two disputed claim terms, while the parties dispute one claim term in the '688 Patent.

The Otterbeck patents cover a controlled release pellet formulation containing mesalamine for the treatment of the intestinal tract, and associated method of treatment claims. The '688 Patent covers methods of maintaining remission of ulcerative

[1] The Otterbeck patents, which claim priority to a German patent application, share a common specification.

colitis for at least six months with certain dosing and target limitations. Salix uses the formulations and methods described in these patents in a commercial product known as Apriso®.

I. BACKGROUND

In a letter dated May 14, 2015, the defendants, Mylan Pharmaceuticals, Inc. and Mylan, Inc. (collectively, "Mylan"), notified Salix that they had filed an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a 375 mg mesalamine oral extended release capsule ("generic capsule"). Mylan also filed a certification with the FDA alleging that certain claims of the patents-in-suit are invalid, unenforceable, and not infringed by Mylan's manufacture or sale of its generic capsule. Salix responded to Mylan's ANDA by filing this patent infringement action pursuant to the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"). See 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271.

In its complaint, Salix contends that the generic capsule described in Mylan's ANDA infringes claims in the patents-in-suit. The parties have identified three terms from those patents in need of construction for which they have proposed competing claim constructions. They also have submitted 12 agreed claim

constructions. Following a claim construction hearing and full briefing of the issues, for the reasons that follow, the Court adopts the following constructions.

II. LEGAL STANDARDS

The construction of patent claims presents a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the claims, the specifications, and the prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). According to a fundamental principle of claim construction, the invention itself, and the scope of a patentee's right of exclusion, will be defined by the patent's claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."). The description of an invention in the claims, therefore, limits the scope of the

invention. Id.

Claim terms should be construed according to their "ordinary and customary" meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Claim construction therefore requires a court to determine how a person of ordinary skill in the art would have understood the disputed term or phrase. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. at 1314. Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. at 1314-15 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910

(Fed. Cir. 2004)).

Aside from the claims themselves, the specification in the patent often provides the "'best source for understanding a technical term.'" Id. at 1315 (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Pursuant to 35 U.S.C. § 112, ¶ 1, an inventor must use the specification to describe his claimed invention in "full, clear, concise, and exact terms." Accordingly, "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940).

An inventor may alter the "ordinary and customary" meaning of a term, however, by acting as his own lexicographer. This occurs, for example, when the patent specification defines a term in a manner different from its ordinary and customary meaning. Phillips, 415 F.3d at 1316. Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

Nevertheless, a court may not import a limitation into the claims from the specification. Id. at 1323. Moreover, the Federal Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. Id. In

other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. Id. (citing Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

The prosecution history of a patent may also provide insight into the meaning of a term or phrase. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. The inventor's limitation of the invention during the patent's prosecution may suggest that a claim has a narrower scope than it otherwise might have. Id.

Finally, when determining the ordinary and customary meaning of a term, a court must be cautious when considering extrinsic evidence, such as expert testimony, dictionaries, and learned treatises. Id. Nevertheless, such sources may be reliable if they were publicly available and establish "'what a person of skill in the art would have understood disputed claim language to mean.'" Id. at 1314 (quoting Innova, 381 F.3d at 1116).

It is with these legal principles in mind that the Court turns to the construction of the disputed terms in the patents-in-suit.

III. ANALYSIS

A. "Core"

The term "core" appears in Claim 1 of the '620 and '886 Patents, and Claims 12 and 24 of the '965 Patent. Salix argues that "core" needs no construction because a person of ordinary skill in the art would readily understand its meaning (Dkt. Nos. 75, 99). Mylan contends that "core" should be defined as "a composition which achieves controlled release of the active compound in the intestinal tract without the aid of a coating." (Dkt. Nos. 74, 101).

1. The Claims

The parties agree that the plain language of the claim includes both a core and a coating. They disagree, however, as to whether the coating contributes to the product's controlled release profile. Claim 12 of the '965 Patent[2] reads as follows:

> 12. A **controlled release pellet formulation** comprising:
>
> 1) 5-aminosalicylic acid **in a core comprising a polymer matrix**, wherein the polymer matrix is essentially insoluble in the intestinal tract and permeable to intestinal fluid, and wherein the polymer matrix comprises at least 1% by weight of the total weight of the core; **and**
>
> **an enteric coating;**

[2] Claim 12 is representative of the claims in the Otterbeck patents involving the term "core."

> wherein about 10-30% of the 5-aminosalicylic acid is released from the formulation in about 30 minutes at 37○ C. in artificial intestinal juice at a pH of about 6.8.

'965 Patent, col. 10:19-28 (emphasis added). The plain language of the claim states that the controlled release profile consists of both the core and the coating. See Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997) (citing In re Baxter, 656 F.2d 679, 686 (C.C.P.A. 1981)) (explaining that "comprising" is a term of art meaning that the named elements are essential, but that other elements may be added and still form a construct). Mylan's proposed definition, which attempts to read out the coating entirely, conflicts with the claim language. See Phillips, 415 F.3d at 1312 ("It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." (internal quotation marks and citations omitted)).

Rather than focus on the language of the claim, Mylan argues that the Court should utilize the construction of "core" adopted by the Honorable Gregory M. Sleet, United States District Judge in the District of Delaware, in Salix Pharms. Inc. v. Novel Labs., Inc., No. 1:14CV213, 2015 WL 4240967, at *2 (D. Del. July 10, 2015) ("the Novel case"). There, Judge Sleet construed the term "core" to mean "a composition which achieves controlled release of the active

compound in the intestinal tract without the aid of a coating," the same construction urged by Mylan (Dkt. No. 74-6 at 2).

This Court has held that another judge's claim construction ruling is not a final order having preclusive effect. Dey, L.P. v. Teva Parenteral Med., Inc., 958 F. Supp. 2d 654, 672 (N.D.W. Va. July 17, 2013). This is particularly the case with Novel, which has yet to be litigated to a final judgment. Kollmorgen Corp. v. Yaskawa Elec. Corp., 147 F. Supp. 464, 467 (W.D. Va. 2001). For reasons the Court will later discuss, it declines to adopt Judge Sleet's construction of "core," which is based solely on the prosecution history.

2. The Specification

The specification in the Otterbeck patents mirrors the language from the claim, supporting Salix's position that both a "core" and a "coating" contribute to the controlled release profile of Apriso®. The specification in the Otterbeck patents reads, in part, as follows:

> The present invention thus relates to an orally administrable pharmaceutical pellet formulation **having a controlled release profile** for the treatment of the intestinal tract, **which comprises a core and an enteric coating** . . . .
> '620 Patent, col. 3:1-4 (emphasis added).

> The active compound is preferably homogeneously dispersed in the matrix described above and is **released with a**

> **delay after dissolving the enteric coating**.
> '620 Patent, col. 4:10-12 (emphasis added).

The specification also provides examples of four pellet coatings and two pellet cores, noting that "[t]he different cores can be combined in any desired manner with the different coatings . . . ." '620 Patent, col. 5:35-38.

After a careful review of the specification, it is clear that the controlled release profile of Apriso® consists of two parts: a core and an enteric coating. The fact that four different coatings are listed in the examples is unavailing; although different coatings can be combined with different cores, some coating is always used in conjunction with a core.

3. The Prosecution History

Mylan's strongest argument relies on the prosecution history of the patents-in-suit. In the Novel case, Judge Sleet found that the patentee had disclaimed cores that worked in conjunction with coatings to achieve controlled release (Dkt. No. 74-6 at 2). He clarified that the claims include an enteric coating, but that the coating does not play a role in the controlled release of mesalamine in the intestinal tract.[3] Id. at 3, n. 1. He stated

[3] Even if the enteric coating dissolves in a patient's stomach, as opposed to the intestinal tract, the Court finds Mylan's argument unavailing. The plain language of the claim does not restrict "the controlled release profile" to only the component

that his "construction is intended to hold the patentee to its prosecution history." Id.

Judge Sleet focused on the September 6, 2006, Amendment and Response to Office Action regarding the Otterbeck patents, in which the patentee distinguished the following prior art: (1) a soluble, degrading matrix; (2) an insoluble polymer coating, as opposed to an insoluble polymer core; and (3) an enzymatically degraded matrix core (Dkt. No. 74-8 at 6-7). As to the second piece of prior art, the patentee explained that the prior art had disclosed a core containing the active pharmaceutical ingredient ("API") with a coating around the core. Because the coating was insoluble, osmotic pressure drove the API through the exterior coating.

In contrast, the Otterbeck patents describe an insoluble polymer matrix core containing the API. After the enteric coating dissolves, intestinal fluids reach the API; it is therefore unnecessary to osmotically drive the API through an insoluble coating. With that background, the patentee stated that "**in the present application the release control is achieved by an insoluble core and not by a coating**, and the core is not dissolved or destroyed during the release of the active ingredient but remains

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of the product that dissolves in the intestinal tract.

intact." Id. at 8 (emphasis added).

The patentee's statement, when viewed in context, is consistent with the clear language of the claim terms and specifications. See Phillips, 415 F.3d at 1317 ("Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes."). The patentee clearly was distinguishing the prior art, which revealed an insoluble polymer coating used to control release of the API, rather than disavowing any coating that works in conjunction with the core. This isolated statement relied on by Mylan falls short of the "clear and unmistakable disavowal" needed to overcome "the heavy presumption that claim terms carry their full ordinary and customary meaning." Biogen Idec, Inc. v. GlaxoSmithKline LLC, 713 F.3d 1090, 1095 (Fed. Cir. 2013) (internal citations and quotation marks omitted). The Court therefore **ADOPTS** Salix's proposed construction and **CONSTRUES** the term "core" consistent with its plain and ordinary meaning.

B. "Non gel-forming polymer matrix"

The term "non gel-forming polymer matrix" appears in Claim 1 of the '620 Patent and Claim 19 of the '886 Patent. Salix urges

the Court to construe the term as "a polymer material that does not **form a surface gel barrier** when in contact with fluid, and can be used for incorporation of, and controlled release of, an active agent." (Dkt. No. 75 at 17) (emphasis added). Mylan argues that the Court should construe the term as "a polymeric material that does not **become a gel** when in contact with fluid, and can be used for incorporation of, and controlled release of, an active agent." (Dkt. No. 74 at 21) (emphasis added).

1. The Claim

Salix and Mylan dispute whether a polymer material does not "form a surface gel barrier" or does not "become a gel" when in contact with fluid.[4] Claim 1 states as follows:

> 1. An orally administrable pharmaceutical pellet formulation having a controlled release profile for the treatment of the intestinal tract, which comprises a core and an enteric coating and optionally pharmaceutically tolerable additives, the core including, as a pharmaceutical active compound, aminosalicylic acid or a pharmaceutically acceptable salt, wherein the active compound is present in the core **in a non gel-forming polymer matrix** which is essentially insoluble in the intestinal tract . . . .
> '620 Patent, col. 9:30-33 (emphasis added).

According to Mylan, Salix's proposed construction deviates from the plain language of the claim, and is inconsistent with the

[4] Mylan does not dispute Salix's use of the word "polymer" rather than "polymeric."

intrinsic evidence. Salix contends that its proposed construction, which is more precise than Mylan's, stems from the prior art distinguished in the patent specification.

2. The Specification

Salix urges the Court to look at the content of the prior art, French patent FR-A2 692 484, to construe the claim. It is well-settled, however, that it is "unnecessary, and indeed improper" for the Court to consider prior art "when the disputed terms can be understood from a careful reading of the public record." Vitronics, 90 F.3d at 1584. The prior art may not "be used to vary claim terms from how they are defined, even implicitly, in the specification or file history." Id. at 1584-85. Because the claim and the specification clearly support Mylan's proposed construction, the Court will not consider the prior art aside from the quotations contained in the specification.

In the specification, the patentee distinguished the invention from the prior art French patent:

> [The prior art] discloses a tablet for the controlled release of 4-ASA in a hydrophilic matrix which consists of swellable polymers **forming a gel barrier**, and having an enteric coating. After dissolution of the coating, the matrix swells and forms a gel barrier through which the active compound diffuses out.
> '620 Patent, col. 1:52-54 (emphasis added).

In the same specification, however, the patentee describes the

prior art in a manner that supports Mylan's proposed construction:

> The use of a **swellable, gel-forming matrix** such as described in [the prior art] is not suitable for pellets having a diameter of [≤]3 mm, since on account of the small diameter the polymer is very rapidly penetrated by the water, eroded as a result, and the active compound would thus be released virtually immediately (about 30 min).
> '620 Patent, col. 2:52-57 (emphasis added).

Importantly, the specification refers to the instant invention as a "non gel-forming polymer matrix," which also supports Mylan's proposed construction:

> In the context of the present invention, however, it has surprisingly been found that, if the active compound is present in the pellet core in a **non gel-forming polymer matrix** which is essentially insoluble and permeable to intestinal fluids and the active compound, a markedly reduced release of the active compound into the blood, with simultaneously increased local concentration of the active compound at the site of the disorder in the intestine, is guaranteed in comparison with aminosalicylic acid formulations already known in the prior art.
> '620 Patent, col. 2:58-67 (emphasis added).

In short, Salix is unable to point to any intrinsic evidence supporting its construction save one reference to a "gel barrier" distinguishing the prior art.[5] Although the patent uses the terms

[5] Judge Sleet's construction of this claim term in Salix Pharms. Inc. v. Lupin Ltd., Case No. 1:12CV1104, is identical to Mylan's proposal. Although Judge Sleet thoroughly analyzed the claim term before adopting the same construction urged by Mylan here, he did not deal with the issue currently before the Court. He also stated that a polymer matrix claimed in the invention "either forms a surface gel barrier . . . or it does not." (Dkt.

"gel barrier" and "gel-forming matrix" to describe the prior art, it never qualifies the gel barrier as a "surface gel barrier," as urged by Salix. Salix's proposed construction would seemingly narrow the claim; it has yet to offer a satisfactory explanation for why the patent should exclude a polymeric "surface gel barrier," but not any polymeric material that "becomes" a gel. Mylan's construction, on the other hand, tracks the language of both the claim and the specification.

The Court therefore **ADOPTS** Mylan's proposed construction and **CONSTRUES** the term "non gel-forming polymer matrix" to mean "a polymeric material that does not become a gel when in contact with fluid, and can be used for incorporation of, and controlled release of, an active agent."

C. "Remission is defined as a DAI score of 0 or 1"

The term "remission is defined as a DAI score of 0 or 1" appears in Claims 1 and 16 of the '688 Patent. Generally speaking, the term "DAI" in the context of ulcerative colitis ("UC") refers to the Sutherland Disease Activity Index ("SDAI" or "DAI"), an assessment used to quantify the clinical symptoms of UC (Dkt. No 74 at 27; Dkt. No 75 at 23). Some large clinical studies utilize the

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No. 74-4 at 11). This statement seems to be a source of Salix's proposed construction, which it claims merely clarifies the construction adopted in the Delaware litigation.

DAI, which is comprised of four variables: stool frequency; rectal bleeding; mucosal appearance; and physician's rating of disease activity. Id.

Salix construes "remission is defined as a DAI score of 0 or 1" to mean "remission is defined as **a rectal bleeding subscore of 0 and a mucosal appearance subscore of less than 2**" (Dkt. Nos. 75, 99) (emphasis added). Salix argues that its proposed construction is consistent with the specification and prosecution history of the '688 Patent. Id. Mylan construes the same claim term to mean "remission is defined as **a DAI score of 0 or 1 as calculated by the four subscores based on stool frequency, bleeding, mucosal appearance on endoscopy, and physician's rating of disease activity**" (Dkt. Nos. 74, 101) (emphasis added). Mylan contends that the claims, specification, and prosecution history of the '688 Patent support its proposed construction. Id.

1. The Claims

The plain language of Claims 1 and 16 explicitly states that "remission is **defined as** a DAI score of 0 or 1." '688 Patent, col. 34:11-18; col. 35:4-13 (emphasis added). The claims thus expressly define the word "remission" (as "a DAI score of 0 or 1"). The claims do not, however, define the phrase "DAI score of 0 or 1"; nor do they explain how to calculate that score using the index.

Accordingly, the nuanced issue on which the parties disagree is how the language "DAI score of 0 or 1" should be construed. In other words, the parties specifically dispute the meaning of "DAI score" and how DAI score is calculated in the context of "remission." In relevant part, Claims 1 and 16 of the '688 Patent provide:

> 1. A method of maintaining the **remission** of ulcerative colitis in a subject comprising administering to the subject a granulated mesalamine formulation . . . wherein: said method maintains **remission** of ulcerative colitis in a subject for a period of at least 6 months of treatment; **remission is defined as a DAI score of 0 or 1** . . . .
>
> 16. A method of maintaining the **remission** of ulcerative colitis in a subject comprising advising the subject . . . wherein: said method maintains **remission** of ulcerative colitis in a subject for a period of at least 6 months of treatment; **remission is defined as a DAI score of 0 or 1** . . . .

'688 Patent, col. 34:11-18; col. 35:4-13 (emphasis added).

Rather than focus on the language of the claims, Salix argues that the specification and prosecution history support its position that "DAI score of 0 or 1" as claimed refers to the sum of only **two subscores** of the index (i.e., rectal bleeding and mucosal appearance) (Dkt. 75 at 21). Specifically, it argues that the patentee acted as his own lexicographer in defining "remission" as "a rectal bleeding subscore of 0 and a mucosal appearance subscore

of less than 2" throughout the specification. Id.

Mylan, however, argues that the claim language, "a DAI score of 0 or 1," refers to a subject's **total** DAI score (i.e., the sum of all four subscores) (Dkt. No 74 at 26-27). According to Mylan, the plain language of the claim reveals that the patentee acted as his own lexicographer by explicitly defining "remission" in the claim: "remission is **defined as** a DAI Score of 0 or 1." Id. (emphasis added). Mylan thus argues that this "explicit definition" controls. Id. at 27. The Court disagrees.

Because the '688 Patent lacks any definition or explanation of "DAI score" or "DAI score of 0 or 1" in the claim language, the entirety of the term "remission is defined as a DAI score of 0 to 1" is not "explicitly" defined in the claims. Additionally, counsel for Salix explained during oral argument that multiple "disease activity indices" are used to assess UC (Dkt. No. 114 at 23). She further indicated that there is "confusion in the field" regarding which index is to be used and what is specifically meant by the term "DAI." Id.

Undoubtedly, the words of a claim "are generally given their ordinary and customary meaning." Phillips, 415 F.3d at 1312. The Federal Circuit has made clear that the ordinary and customary meaning of a claim term is "the meaning that the term would have to

a person of ordinary skill in the art in question at the time of the invention." Id. at 1313. Importantly, the person of ordinary skill in the art (or "POSA") is deemed to read the claim term "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. The court must therefore "review[] the same resources as would that person, viz., the patent specification and the prosecution history." Id. (citing Multiform Desiccants, 133 F.3d at 1477). See also Kinik Co. v. Int'l Trade Comm'n, 362 F.3d 1359, 1365 (Fed. Cir. 2004) ("The words of patent claims have the meaning and scope with which they are used in the specification and prosecution history.").

Moreover, although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and "use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics, 90 F.3d at 1582. See also Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (Fed. Cir. 1990) ("It is a well-established axiom in patent law that a patentee is free to be his or her own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary

meanings.") (citations omitted)). In such a case, the definition selected by the patent applicant controls. Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998). It is thus "always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Vitronics, 90 F.3d at 1582. The specification "acts as a dictionary" when it expressly defines terms used in the claims or when it defines terms by implication. Id. (citing Markman, 52 F.3d at 979).

Finally, although it is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled to exclude" (Phillips, 415 F.3d at 1312), the claims "do not stand alone." Id. at 1315. Rather, they are "part of a fully integrated instrument," consisting primarily of a specification that concludes with the claims. Id. (citing Markman, 52 F.3d at 978). Accordingly, claims "must be read in view of the specification, of which they are a part." Id. See also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("In most cases, the best source for discerning the proper context of claim terms is the patent specification"); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985) ("The descriptive part of the specification aids in

ascertaining the scope and meaning of the claims inasmuch as the words of the claims must be based on the description.").

Both Salix and Mylan ultimately contend that the patentee elected to be his own lexicographer by providing an explicit definition in the specification for the claim term (Dkt. No. 75 at 21; Dkt. No. 74 at 26-27). If the patentee provided such a clear definition, reference to the specification is required "because only there is the claim term defined as used by the patentee[]." Renishaw, 158 F.3d at 1249. Because the disputed claims "explicitly recite[] a term in need of definition" (i.e., the term "a DAI score of 0 or 1"), the claims are "susceptible to clarification by the written description," and a definition "may enter the claim[s] from" that description. Id. at 1248.

For these reasons, the Court must consider Claims 1 and 16 together with the rest of the specification to determine what "remission is defined as a DAI score of 0 to 1" means.

2. The Specification

Salix points to repeated references to "remission" in the '688 patent's specification to establish that the patentee intended to define "remission" to mean "a rectal bleeding subscore of 0 and a mucosal appearance subscore of less than 2." Meanwhile, Mylan relies upon a single reference to the DAI in the larger context of

"ulcerative colitis disease activity" to argue that the '688 specification supports its proposed construction.

Salix contends that, throughout the specification, the patentee explicitly and repeatedly defined "remission." Specifically, it argues that "remission" is consistently defined as a "rectal bleeding score of 0 and a mucosal score of less than 2" (Dkt. No. 75 at 2). The specification in the '688 Patent reads, in part, as follows:

> "Patients with documented UC **remission** (**revised Sutherland Disease Activity Index [DAI] subscores: rectal bleeding 0; mucosal appearance <2**) were randomized 2:1 to receive 1.5 g granulated mesalamine . . . ."
> '688 Patent, col. 6:53-58 (emphasis added).
>
> "Pooled patients . . . with documented UC **remission** (**revised Sutherland Disease Activity Index [DAI] subscores: rectal bleeding 0; mucosal appearance <**2) . . . ."
> Id. at col. 25:32-35; 26:21-24 (emphasis added).
>
> "Patients . . . in **remission** with ulcerative colitis (**revised Sutherland Disease [SDAI] subscores: rectal bleeding 0; mucosal appearance <2**) . . . . ."
> Id. at col. 26:51-53(emphasis added).
>
> "**Remission** was defined as **both** a screening **rectal bleeding score of 0** (no bleeding) and a screening sigmoidoscopy **score for mucosal appearance of 0 . . . or 1** . . . . ."
> Id. at Example 10, col. 28:3-5(emphasis added).

Salix contends that each instance where "remission" is discussed in the specification reveals that the patentee "expressly

limited [his] definition to mean rectal bleeding with a subscore of zero and a mucosal appearance score of less than 2." (Dkt No. 75 at 17). It argues that because the patentee acted as his own lexicographer, his explicit definition controls. Id. Accordingly, Salix contends that Mylan's proposed construction, which would define remission using the sum of all four subscores, improperly deviates from the patentee's express definition of "remission." Id. at 23.

Salix also notes that "relapse" (the opposite of "remission") is consistently and repeatedly defined in the specification as "a rectal bleeding subscore of **one or more** and a mucosal subscore of **2 or more**." Id. at 17 (emphasis added). See, e.g., '688 Patent, col. 6:53-57, col. 25: 32-35; col. 28: 3-8. Because "relapse" is the opposite of "remission," Salix argues that these instances support its contention that "remission" has the inverse definition of "relapse" (i.e., "remission" as rectal bleeding with a subscore of **zero** and a mucosal appearance score of **less than 2**). Id. In other words, the same two subscores (rectal bleeding and mucosal appearance) are used consistently throughout the '688 Patent to describe "relapse" and "remission" as inverse terms.

Mylan nevertheless argues that the '688 specification supports its proposed construction. It relies heavily on a single paragraph

in one example that reads as follows:

> **Ulcerative colitis disease activity** was assessed using a **modified Sutherland Disease Activity Index1 (DAI),** which is a **sum of four subscores based on stool frequency, rectal bleeding, mucosal appearance on endoscopy, and physician's rating of disease activity**. Each subscore can range from 0 to 3, for a total possible DAI score of 12.

'688 Patent, Example 5, col. 17:2-11 (hereinafter "Example 5")(emphasis added).

According to Mylan, Example 5 provides an "explicit definition" for the meaning and calculation of "DAI score" as used in the claims (Dkt. No. 74 at 27). Specifically, it argues that Example 5 demonstrates that the language "DAI score of 0 or 1" as claimed refers to a **total** DAI score of 0 or 1, as calculated by summing the four subscores.[6] Id. Mylan also notes that when the patentee added the language "remission is defined as a DAI score of 0 or 1" to the claims, he cited to Example 5, stating that "support can be found in Example 5, entitled 'Studies on Remission from Ulcerative Colitis.'" Id.

Mylan's proposed construction, however, is grounded solely in

[6] Mylan also points out that Example 10 provides a similar definition for the SDAI: "[The index] evaluates stool frequency, rectal bleeding, mucosal appearance, and physician's rating of disease severity on scales of 0 to 3, with a maximum total score of 12"(Dkt. No. 74 at 27).

the general description of the DAI—an index used to assess "ulcerative colitis disease activity"—as outlined in the first paragraph of Example 5. Notably, this paragraph does **not** define (nor even refer to) "remission"; nor does it explain DAI score (or subscores) in the context of remission. Moreover, Mylan fails to acknowledge that Example 5, upon which its specification argument is almost entirely based, additionally states, "**[r]elapse**, as used herein, included, for example, **a rectal bleeding subscore of 1 or more and a mucosal appearance subscale score of 2 or more using the DAI**." '688 Patent, Example 5, col. 17:15-18 (emphasis added). This portion of Example 5 lends credence to Salix's arguments that (1) the terms "relapse" and "remission" are expressly and consistently defined throughout the specification in terms of two subscores (rectal bleeding and mucosal appearance), and (2) the description of the DAI in the first paragraph of Example 5 refers only to a generalized description of means used to assess various aspects of UC disease activity. Id.

Mylan's proposed construction ultimately contradicts the explicit, repeated definition of "remission" used by the patentee. Throughout the specification, the patentee expressly and consistently defined "remission" in terms of specific DAI subscores. In particular, the patentee defined "remission" as a

rectal bleeding score of 0 and a mucosal appearance subscore of less than 2. By clearly stating the special definition of the term in the patent specification, the patentee chose to act as his own lexicographer, and this definition is thus controlling. Phillips, 415 F.3d at 1316.

Mylan's additional argument for its proposed construction of the claim term relies on the litigation history of the '688 Patent. In Novel, the court construed the term "remission is defined as a DAI score of 0 or 1" to mean the language proposed here by Mylan. Judge Sleet noted:

> This claim term is, itself, an express definition. It tells the court exactly how to construe "remission." In relevant part, Claim 1 claims: "A method of maintaining the remission of ulcerative colitis in a subject . . . wherein: . . . remission is defined as a DAI score of 0 or 1."

Novel, 2015 WL 4240967, at *2, n.3. As previously discussed, however, a prior construction of the term in the Novel litigation does not have a preclusive effect in this case. Dey, 958 F. Supp. 2d at 672. Because Judge Sleet's construction contradicts the specification (and, as discussed in subsection 3, the prosecution history) of the '688 Patent, the Court declines to adopt it.

Although Judge Sleet found that the claim term itself "tells the court exactly how to construe 'remission,'" he also stated in the same footnote that "the **court need only reference the**

specification [at Example 5] to determine how a DAI score is calculated." Novel, 2015 WL 4240967, at *2, n.3. In that sense, Judge Sleet's observations are consistent with Salix's position that, although the plain language of the claims explicitly defines "remission," it does **not** explicitly define or explain "DAI score of 0 or 1" or how DAI score is calculated. Accordingly, the Court declines to find that the claim term in its entirety constitutes an express definition.

Moreover, this Court declines to rest its entire analysis of the '688 specification solely on the first paragraph of Example 5, which ultimately refers to a generalized description of the assessment means (i.e., the modified Sutherland DAI), rather than the specific DAI parameters used by the patentee to define "remission." Rather, an examination of the entirety of the '688 Patent leads to the conclusion that the patentee expressly and repeatedly defined "remission" to mean "a rectal bleeding score of 0 and a mucosal appearance subscore of less than 2" throughout the specification.

In sum, "remission" was consistently defined throughout the specification to mean the subscores of rectal bleeding and mucosal appearance (and not the sum of all DAI subscores). Accordingly, when taken together, the claims and specification support Salix's

proposed construction. Merck & Co. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("[T]erms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part"); Renishaw, 158 F.3d at 1249 ("The construction that stays true to the claim language and most naturally aligns with the patent's description . . . will be, in the end, the correct construction.").

3. The Prosecution History

Salix's proposed construction is further supported by the prosecution history of the '688 Patent. The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications "not solely on the basis of the claim language," but also "in light of the specification as it would be interpreted by one of ordinary skill in the art." Phillips, 415 F.3d at 1316 (citing In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004)). Based on the record, the patent examiner and patentee understood that a "DAI score of 0 or 1" meant a "rectal bleeding subscore of 0 and a mucosal appearance subscore of less than 2" on the DAI.

In a summary report of a 2012 applicant-initiated interview regarding the rejection of pending claims, the patent examiner

noted that the patentee would "consider amending claims . . . to further define the subject population in having a Sutherland Score of 0 or 1" (Dkt. No. 75 at 21-22). The report goes on to state that "**[r]emission** was defined as both a screening **rectal bleeding score of 0** (no bleeding) and a screening sigmoidoscopy **score for mucosal appearance of 0 . . . or 1** . . . on the revised Sutherland Disease Index (SDAI)." Id. at 22 (emphasis added). The patentee then amended the claims to add "remission is defined as a DAI score of 0 or 1" (the language in Claims 1 and 16), noting that "support can be found in the examples and **throughout the specification**." Id. (emphasis added). These statements, together with the specification, demonstrate that both the patent examiner and patentee understood "DAI score of 0 or 1" to mean a "rectal bleeding subscore of 0 and a mucosal appearance subscore of less than 2."

For the reasons discussed, the Court **ADOPTS** Salix's proposed construction and **CONSTRUES** "remission is defined as a DAI score of 0 or 1" to mean "remission is defined as a rectal bleeding subscore of 0 and a mucosal subscore of less than 2."

IV. CONCLUSION

The Court **CONSTRUES** the contested claim terms as follows:

1. "Core" is to be given its plain and ordinary meaning;
2. "Non gel-forming polymer matrix" means "a polymeric material that does not become a gel when in contact with fluid, and can be used for incorporation of, and controlled release of, an active agent"; and
3. "Remission is defined as a DAI score of 0 or 1" means "remission is defined as a rectal bleeding subscore of 0 and a mucosal subscore of less than 2."

Further, the Court adopts the parties' agreed claim constructions and **CONSTRUES** the following terms and phrases as follows:

1. "Matrix-forming polymer" means "polymers, except pH-sensitive enteric polymers, that are used to form the non gel-forming polymer matrix";
2. "Essentially insoluble" is to be given its plain and ordinary meaning;
3. "Pharmaceutically tolerable additive(s)" is to be given its plain and ordinary meaning;
4. "About," as in about # hours, is to be given its plain and ordinary meaning;

5. "About, as in about # mm, is to be given its plain and ordinary meaning;
6. "About five hours" is to be given its plain and ordinary meaning;
7. "Mean maximal plasma concentration of the 5-aminosalicylic acid is reached" is to be given its plain and ordinary meaning;
8. "Homogeneously dispersed" is to be given its plain and ordinary meaning;
9. "Without food" is to be given its plain and ordinary meaning;
10. "Wherein: said method maintains remission of ulcerative colitis in a subject for period of at least 6 months of treatment" is to be given its plain and ordinary meaning;
11. "Pellet(s)" is to be given its plain and ordinary meaning; and
12. "Wherein 85 to 90% of the mesalamine reaches the terminal ileum or colon" is to be given its plain and ordinary meaning.

It is so **ORDERED**.

The Court **DIRECTS** the Clerk to transmit copies of this Order to counsel of record.

DATED: April 12, 2016.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE